

### Remarks

After amendment, claims 1-6 and 13-38 are pending in the present application. Claims 19-24 represent the same subject matter from original claims 7-12 (pharmaceutical composition claims), except that the form of the claims has been modified to make these claims dependent on claims 1-6. Claims 19-24 also address the Examiner's concerns regarding the inclusion of an optional carrier, additive or excipient, which in pharmaceutical composition claims is no longer optional. Claim 18 has been amended to point out that the method is now directed to reducing the likelihood of a recurrence of breast cancer, a method clearly taught and enabled by the present invention. Note that the claims have been amended to avoid the originally filed claims from reading on the compounds which are disclosed in the cited art. Support for the amendment to the original claims can be found throughout the original specification and claims. Note that all of the subject matter which is now found in the claims was set forth in the originally filed claims.

The Examiner has rejected originally filed claims 1-18 variously under 35 U.S.C. §112, first and second paragraphs, double patenting and §102 and §103, for the reasons which are stated of record in the September 29, 2005 office action. Applicant shall address each of the Examiner objections/rejections in the sections which follow.

#### The §112, First Paragraph Rejection of the Claims

The Examiner has rejected claim 18 as being unpatentable over 35 U.S.C. §112, first paragraph as being directed to subject matter which is non-enabled. Essentially, it is the Examiner's contention that originally filed claim 18, which included a method of reducing the likelihood of a patient contracting breast cancer was non-enabled, inasmuch as there is no teaching in the art for the prevention of cancer and there is no known method for the determination that a person is susceptible to breast cancer.

In response to the Examiner's contention, claim 18 has been amended and new claim 38 has been added to reflect a method of reducing the likelihood of a *recurrence* of breast cancer comprising administering an effective amount of a compound according to claim 1 or claim 25 to said patient. Inasmuch as one of ordinary skill will readily be able to determine that a patient has had breast cancer, the administration of a compound according to the present invention to *reduce the likelihood* of a recurrence in a patient who has already had breast cancer is clearly enabled by

the present invention.

#### The §112, Second Paragraph Rejection of the Claims

The Examiner has rejected originally filed claims 1, 2, 5-9, 11, 12 and 17 under 35 U.S.C. §112, Second Paragraph for the reasons which are stated in the office action on pages 3-4. Note that the amended claims address all of the issues which the Examiner raised in her office action. Note also that claims 7-12 have been cancelled. Applicant respectfully submits that the amended claims are now in complete conformity with the requirements of 35 U.S.C. §112, Second Paragraph.

It is respectfully submitted that the claims, after amendment fully comply with the requirements of 35 U.S.C. §112, second paragraph.

#### The Double Patenting Rejection

The Examiner has rejected claims 10-12 as being a substantial duplicate of claims 4-6, respectively. Inasmuch as Applicants has cancelled claims 10-12 and the claims which replace those claims (which fall within claims 19-24) are directed to pharmaceutical compositions, it is respectfully submitted that Applicant has addressed the concerns of the Examiner.

#### The §102 Rejections

##### The Rejection over Jelinkova, et al.

The Examiner has rejected original claims 1,3,4,7,9 and 10 under 35 U.S.C. §102(b) as being anticipated by Jelinkova, et al. ("Jelinkova"). The Examiner cites Jelinkova for teaching 11 $\beta$ -methoxymethyl-17- $\alpha$ -ethinyl-1,3,5(10)-oestratriene-3,17 $\beta$ -diol and its estrogenic activity.

Note that the instant application is now directed to compounds, pharmaceutical compositions and methods of use which distinguish over the Jelinkova cited reference and in particular, the compound disclosed by Jelinkova which the Examiner has indicated anticipates the present invention. Jelinkova cannot be seen to anticipate the instant invention, especially inasmuch as the ether substituent at the 11 position of the claimed compound is significantly

longer (by two atom units) than is the methoxymethylether side-chain of Jelinkova (which chain has only three atoms in the ether chain). Consequently, Jelinkova clearly does not anticipate the presently claimed invention.

#### The Rejection over Agarwal, et al.

The Examiner has rejected claims 1, 3, 7 and 9 as being anticipated by Agarwal, et al. ("Agarwal"). The Examiner cites various analogs of Agarwal and cites in particular, the compound, 11 $\beta$ -(2-methoxyethyl)-1,3,5(10)-oestratriene-3,17 $\beta$ -diol and its effect on glucocorticoid action. Inasmuch as the ether substituent at the 11 position of the claimed compound is longer than is the ether side chain of the Agarwal compound, the claimed invention is clearly not anticipated by Agarwal.

#### The §103 Rejection

The Examiner has rejected originally filed claims 13-17- as being unpatentable over Jelinkova for the reasons which are stated in the office action. Essentially, it is the Examiner's position that because Jelinkova discloses that 11 $\beta$ -methoxymethyl-17- $\alpha$ -ethinyl-1,3,5(10)-oestratriene-3,17 $\beta$ -diol exhibits estrogenic activity in the disclosed rat endometrium lactate dehydrogenase assay, that makes it *prima facie* obvious to use the same compound in the various claimed methods.

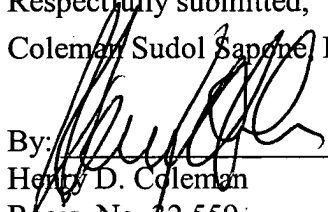
Note that the claims are now directed to compounds which clearly distinguish over the analogue which is cited by the Examiner in Jelinkova. Inasmuch as the *closest* claimed compound of the present invention is substantially different from the Jelinkova compound by virtue of the length of the ether side chain at the 11 position of the claimed compound, Jelinkova does not disclose any of the methods which are even related to the present invention and Jelinkova does not disclose any structure activity relationship from which one may glean activity associated with related compounds, it is respectfully submitted that the instant claims are clearly patentable over the Jelinkova reference. Note that the Examiner's original rejection under 35 U.S.C. §103 was made based upon the fact that the original claims were directed to a method which utilized the specifically cited compound in Jelinkova. Inasmuch as the presently amended claims clearly distinguish over the cited compound in Jelinkova and make use of the patentably distinguishable compounds, it is respectfully submitted that amended claims 13-17 and

corresponding method claims 33-37 of the present application are clearly non-obvious and patentable over the cited prior art.

For the above reasons, Applicant respectfully asserts that the claims set forth in the amendment to the application of the present invention are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and such action is earnestly solicited. Applicants previously have neither cancelled nor added any claim to the present application.

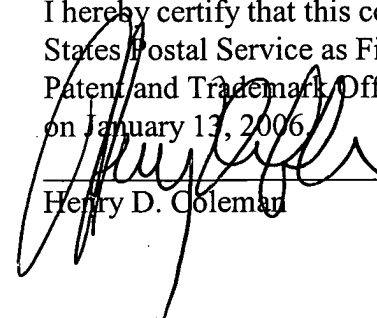
A fee in the amount of \$300 is due and enclosed for the presentation of 12 dependent claims beyond 20 (6 claims, including one independent of the original 18 cancelled, and 18 additional claims (one independent) added (small entity status applies). A petition for a one month extension of time is enclosed as is the \$60 fee. If any additional fee is due or any overpayment has been made, please charge/credit Deposit Account No. 04-0838.

Respectfully submitted,  
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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: "United States Patent and Trademark Office P.O. Box 1450 Alexandria, Virginia 22313-1450" on January 13, 2006.

  
Henry D. Coleman